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10/693,315	10/24/2003	Takao Abe	AM100905P1	1495

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WYETH LLC
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
BERCH, MARK L	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/693,315
Filing Date: October 24, 2003
Appellant(s): ABE ET AL.

Michael Herman
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/03/2010 appealing from the Office action mailed 7/11/2008.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

9-11, 13-30, 32-40

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

Claim 32 is given incorrectly. The next to last line of step (e) is given as "acetic anhydride/organic tertiary" whereas the correct text, as provided in the amendment after final of which was entered, is "acetic anhydride, organic tertiary".

(8) Evidence Relied Upon

7018997	VENKATESAN	03-2006

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claims:

Claims 9-11, 13-30, 32-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7018997.

This appeal presents a single legal issue, viz., the correct standard for overcoming an obviousness-type double patenting rejection.

The patent discloses the compounds. The rejected claims are drawn to the process of preparing those compounds. No restriction was ever made between the two.

Initially, claims to a product, and claims to methods of preparing or using, are not patentably distinct. See ***Geneva Pharmaceuticals Inc. v. GlaxoSmithKline PLC***, 68 USPQ2d 1865; ***In re Boylan,*** 157 USPQ 370; ***In re Byck***, 9 USPQ 205, and ***In re Freeman***, 76 USPQ 585 as examples. It appears that applicants are not disputing this assertion.

The question to be decided is: what is the correct standard for overcoming this rejection. It is the examiner's position that to show that the compound and process inventions are patentably distinct, applicants must demonstrate that there is an alternative method. As was stated in ***Takeda Pharmaceutical Co., Ltd. v. Dudas***, 84

USPQ2d 1365, which applicants cited, applicants must show that there are "alternative processes for making the compounds"; this position was likewise adopted in the successor case ***Takeda Pharmaceutical Co. v. Doll***, 90 USPQ2d 1496. Similar language can be found in ***Phillips Petroleum Company et al. v. U.S. Steel Corp. et al.***, 225 USPQ 1149, ***Ex parte Zoss***, 114 USPQ 309, and as far back as ***In re Cady***, 25 USPQ 345.

Likewise, MPEP §806.05 states that a product and its process are patentably distinct if "the product as claimed can be made by another materially different process."

Applicants have not asserted that there is an alternative process, let alone presented that process, so that the examiner can determine if the assertion is factually accurate. In fact, applicants have to some degree leaned toward the opposite, saying on page 3 of the Appeal Brief, "However, there is no generally conventional process for making the compound of the present invention." (emphasis in the original). Of course, this leaves open the idea that there might (or might not) be a generally unconventional process. Applicants are explicit in not closing the door on that possibility, with a double negative: "but that is not to say that there are not other methods of producing these compounds." Thus, applicants say that there actually isn't another "generally conventional process", but applicants aren't going so far as to say that there are no other methods at all. In the other direction, on page 4, applicants state, "Furthermore, it is highly likely that the compound could be made by other processes." The basis for such a determination is not given.

Clearly, then the standard of specifically setting forth an alternative process has not been met.

Instead, applicants ignore this standard, and propose a different one. Applicants argue that "the process of preparing compounds of the present invention is not obvious from

the claims compounds, method of treatment, or pharmaceutical composition of the '997 patent."

The claimed synthetic process here is in fact the same process as is in the patent, which is why the above quote does not refer to the synthesis.

The process is not obvious from any reference for that matter. The compound claims were found unobvious and under ***In re Ochiai***, 37 USPQ2d 1127 that meant that the method of manufacture claims were pretty much automatically unobvious.

However, all this is beside the point, because this is not the correct standard. Applicants present no case law in defense of their standard for overcoming the nonstatutory obviousness-type double patenting rejection, and the examiner is not aware of any. Nor have applicants complied with the "alternative processes for making the compounds" standard.

Accordingly, applicants have not established the compounds and the process as being patentably distinct, and therefore, the rejection is sound.

(10) Response to Argument

The above section constitutes a full response to all arguments made in the Appeal Brief.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Mark L. Berch/
Primary Examiner, Art Unit 1624

Conferees:

/James O. Wilson/, SPE Art Unit 1624

/Joseph K. McKane/, SPE Art Unit 1626